UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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PEDINOL PHARMACAL, INC.,

Plaintiff,

-against-

RISING PHARMACEUTICALS, INC.,

Defendant.
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MEMORANDUM AND ORDER

CV 06-2120

(Wexler, J.)

APPEARANCES:

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WEXLER, District Judge

This is a case alleging false advertising and unfair competition commenced by Plaintiff Pedinol Pharmacal, Inc. ("Pedinol" or "Plaintiff") against Defendant Rising Pharmaceuticals, Inc. ("Rising" or "Defendant"). Presently before the court is Rising's motion, pursuant to Rule 56 of the Federal Rules of Civil Procedure, for summary judgment. For the reasons set forth below, the motion is denied.

BACKGROUND

I. The Parties and the Product At Issue

Pedinol is a pharmaceutical company specializing in the development, distribution, sales and promotion of pharmaceutical products. Defendant Rising is a pharmaceutical company that competes with Pedinol. Pedinol markets a product sold under the name "Lactinol." Lactinol is Pedinol's brand name for various creams and lotions containing, as their active ingredient, 10% lactic acid. Such products are prescribed by physicians for the treatment of dry skin and other skin conditions. Rising markets a product sold as "10% Lactic Acid."

Pedinol alleges that the lactic acid product marketed by Rising is a "knock off" of the Lactinol product. According to Pedinol, the Rising lactic acid product as not the therapeutic equivalent of Lactinol. Rising is alleged to have made false claims regarding the comparison of its product to Lactinol. Rising is also alleged to have visited with physicians and induced them to improperly and illegally substitute the Rising product for Lactinol. Pedinol asserts that it has lost approximately 60-70% of the Lactinol market due to what it characterizes as "illegal substitutions and/or palming off without any promotion of [Rising's] knock-off product based upon its merits."

Rising, on the other hand, paints a very different picture of the landscape surrounding the prescription and use of lactic acid skin products. According to Rising, there is nothing unique about Plaintiff's product. Rising asserts that Lactinol is neither covered by patent protection nor any other governmentally recognized grant of exclusivity. It is further asserted that the only difference between Rising's lactic acid product and Lactinol is price, with Pedinol charging two to three times more for Lactinol than Rising charges for its product. Rising alleges that Pedinol

falsely represents its product as an FDA-approved brand name product to "continue to engage in its pricing scheme and stifle competitor sales."

II. The Complaint and Counterclaims

Pedinol asserts both federal and state causes of action. Specifically, Pedinol states two causes of action pursuant to Section 43(a) of the Lanham Act, 15 U.S.C. §1117 and 1116. The Lanham Act claims assert false advertising and unfair competition. Pedinol's complaint also sets forth New York State law statutory causes of action, alleging deceptive trade practice and false advertising, pursuant to Sections 349 and 350 of the New York General Business Law. Finally, Plaintiff asserts common law claims for palming off, inducing palming off, misappropriation and unfair competition. Pedinol seeks injunctive relief prohibiting the false advertising of the Rising product as a therapeutic or pharmaceutic equivalent of Lactinol as well as compensatory, statutory and punitive money damages.

Rising's counterclaims assert Lanham Act claims for false advertising and unfair competition. In support of its claims, Rising asserts that Pedinol makes false assertions regarding FDA approval of Lactinol. Like Pedinol, Rising asserts New York State law claims pursuant to the New York General Business Law. Finally, Rising asserts that Pedinol has engaged in unfair competition in violation of New Jersey State law, the state in which Rising is located. Rising seeks injunctive and monetary damages.

III. Rising's Motion and Pedinol's Opposition

Rising moves for summary judgment. Much of its motion relies on the asserted fact that Pedinol markets Lactinol without FDA approval. It is argued that this illegal marketing should prohibit Pedinol's claims for relief from this court. Rising also argues that it cannot be held

liable for inducing illegal substitution of its product, because such substitution is specifically permitted under law.

In response, Pedinol argues that it has lawfully marketed Lactinol, in accord with FDA-recognized exceptions to its approval regulations. It is further argued that Lactinol is manufactured according to exacting specifications and has long been recognized as safe. Finally, Pedinol argues that as a marketer of its own lactic acid product, Rising is in no position to point to the unlawful marketing of Lactinol as a bar to relief. Pedinol stresses that this is a false advertising case. Issues of regulatory compliance are stated to be within the exclusive jurisdiction of the FDA.

DISCUSSION

I. FDA Approval of Drugs

The Federal Food Drug and Cosmetic Act, (the "Act"), enacted in 1938, 21 U.S.C. § 301, requires pre-marketing clearance by the FDA of "new drugs." See generally Weinberger v. Hynsos, Westcott and Dunning Inc., 412 U.S. 609, 611 (1973). Drugs are defined broadly by the Act to include, inter alia, any article used in the diagnosis or treatment of any disease and any article intended to "affect the structure or any function of the human body." 21 U.S.C. § 321(g)(1). Exempt from drugs subject to the 1938 Act were certain drugs subject to the Food and Drugs Act of 1906. 21 U.S.C. § 321(p)(1). Other drugs exempt from the Act are those that have been generally recognized as safe and effective. Such drugs are referred to as "generally accepted as safe and effective," known under the acronym "GRAS/E."

In 1962, the Act was amended to require that new drugs be proven effective as well as safe. The 1962 amendment also contains a clause exempting from the effectiveness requirement

drugs that, prior to the amendment: (1) were commercially used or sold in the United States, (2) were not "new drugs" under the original Act; (3) were not covered by an effective application for a new drug under the Act and (4) were currently intended solely for use under conditions recommended in the drug's pre-1962 labeling. United States v. Vital Health Prods., Ltd., 786 F. Supp. 761, 774 (E.D. Wis. 1992), aff'd., 985 F.2d 563 (7th Cir. 1993); United States v. Articles of Drug Consisting of Following: 5,906 Boxes, 745 F.2d 105, 108 (1st Cir. 1984); see Weinberger, 412 U.S. at 614.

Drugs that do not fall within an FDA exception must be approved by the FDA prior to marketing. With respect to those drugs, the FDA must approve a "new drug application" ("NDA"), prior to lawful marketing. The NDA demonstrates the safety and effectiveness of the drug at issue so that it may be approved by the FDA. Generic equivalents of drugs covered by NDA's may be approved by the FDA by the submission of an "Abbreviated New Drug Application," known as an "ANDA." The ANDA demonstrates the bio-equivalence and pharmaceutical equivalence of the generic drug to the approved drug.

While this statutory scheme may appear simple, the reality of the marketing of drugs is anything but uncomplicated. The fact is that many drugs are in widespread use without FDA approval as "new drugs." This is also the case with respect to generic equivalents of such drugs. The FDA is well aware of the marketing of unapproved drugs. In an agency publication entitled, "Questions and Answers for Consumers about Unapproved Drugs," the FDA recognizes that there are several hundred unapproved prescription active ingredients on the market.[1] FDA

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[1] The FDA publication referred to by the court is available at the FDA website, http://www.fda.gov/cder/drug/unapproved_drugs/qaConsumers.pdf.

acknowledges that such drugs are prescribed by physicians and taken by patients. Examples cited by the FDA of such unapproved drugs include phenobarbital, long used in the treatment of seizures, and commonly used antihistamines. The FDA cannot, as a practical matter, use its enforcement powers to remove all unapproved drugs from the market place at once. Indeed, it appears that such enforcement would do more harm that good since many such drugs are currently in use and provide benefits. Instead, FDA must use its enforcement powers judiciously to protect Americans from unsafe and/or ineffective drugs.

II. Disposition of the Motion

There is no question but that the product at issue here is a "drug" subject to regulation by the FDA. What is less clear is the legality of the current marketing of that drug and the extent to which the realities of the regulatory, prescribing and commercial marketplaces impact on what is "legal." Given the many factual questions before the court regarding the prescription and use of the product at issue, the court cannot conclude that marketing of Lactinol without an approved NDA should be a bar to the relief sought. Factual questions regarding the equivalence of the products at issue bars the entry of summary judgment on any claim regarding illegal substitution. Finally, the court is mindful that this is a false advertising and unfair competition case based upon alleged misrepresentations made concerning the products at issue. Such statements may or may not apply to the regulatory status of the products. The court is simply in no position to tell at this time.

In light of the foregoing, the Court finds that genuine issues of material fact exist precluding the entry of summary judgment with respect to plaintiffs' claims. See Fed. R. Civ. P. 56(c) (a party seeking summary judgment must demonstrate that "there is no genuine issue of any

material fact and that the moving party is entitled to a judgment as a matter of law."); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Donohue v. Windsor Locks Bd. of Fire Comm'rs, 834 F.2d 54, 57 (2d Cir. 1987). The motion for summary judgment is, therefore, denied.

CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment is denied. The Clerk of the Court is directed to terminate the motion.

SO ORDERED.

LEONARD D. WEXLER
UNITED STATES DISTRICT JUDGE

Dated: Central Islip, New York
September, 4 2007